

R E M A R K S

Claims 1 and 3-13 are now in this application, and are presented for the Examiner's consideration.

Prior Art Rejections

Before discussing the specific prior art rejections, the following comments are provided.

In the present invention, the blister is an independent body of a breakable blister having a single chamber made of a flexible wall permanently heat-sealed around a closed line as shown in Figs. 2-4. The blister can be produced, for example, in a continuous manufacturing process as stated at page 1, lines 13-29 of the present application. A conventional type of blister, such as a blister sealed only by a permanent seal, can be used in the present invention.

The blister is housed in the pouch with the pouch completely surrounding the blister on all sides thereof, and the blister is an independent body from the pouch. The pouch, in turn, is further surrounded by a protective cover made of two separable parts of leak-proof material and permanently fixed to one of the inside faces of the protective cover.

The packaging discussed above is also attained in a continuous manufacturing process as well as the blister, and thus provides great improvement from a cost point of view.

In use, the package is compressed before opening the protective cover, e.g. by finger pressure on the center of the closed protective cover. As a result, the blister is broken so that the applicator is impregnated with the substance included therein, as stated in page 2, lines 8-15 and page 6, lines 11-18 of the present application.

In this event, the breaking point of the blister is not specified, and is therefore uncontrolled. Nevertheless, the pouch comprising the applicator is impregnated with most of the quantity of the substance contained in the blister, whatever the breaking point may be. Because the blister is housed inside the pouch, preferably at the central position of the pouch as shown in Figs. 2-4, the applicator will be impregnated with the substance on most of its surface after breakage of the blister. Then, after opening the protective cover, the user can apply the substance onto the skin without touching the substance.

It is important to note that, with this structure, ANY kind of substance, for example, powder, paste, cream, liquid, etc. can be contained in the blister before use and is easily applicable on the skin when in use. In this manner, the package has general versatility.

This is a technologically important point and advantage of the present invention. The usability of the package in the present invention is achieved only upon a simple but rational structure of the package. Further, the package according to the

present invention can be manufactured without complicated processes.

As stated above, with the structure recited in claim 1 herein, there is NO need to control breaking at a specified position on the blister. The present invention enables to utilize an uncontrolled blister package structure where the pouch entirely surrounds the blister as an independent body on all sides, and a further protective cover surrounds the pouch entirely on all sides.

Moreover, the applicator has a convex or rounded shape, as shown in Fig. 3, even if a piece of cotton is not provided therein, so that application of the substance to a desired position on the skin can easily be achieved, even onto a narrow area or spot area, like a wound, with a soft feeling.

Claim 11 is similar to claim 1.

Claim 1 recites that the blister is housed inside the pouch and is held captive therein.

With this structure, not only the blister, but also the outer pouch, can be produced in the same manufacturing line.

Claim 11 further states that "said junction line surrounds an area that is significantly greater than an area occupied by said pouch". The words significantly greater than refer to the arrangement shown, for example, in Fig. 4.

As a consequence, the user can apply a substance like an antiseptic to a wound without touching the peeled-off line,

because the applicator is away from the peeled-off line and peripheral line of the protective cover. Thus, the pain the user might feel in the event of topical treatment to a wound will be greatly reduced. At the same time, the user can apply the substance onto the skin if only he/she holds the protective cover without touching the skin and applicator. Hence, there is no risk of contamination.

If a piece of cotton is further contained inside the pouch in a preferred embodiment, the shape of the applicator is more convex or more rounded, as shown in Fig. 3. Accordingly, the user can apply the substance onto a narrow area, such as a wound, very selectively without pain because the cotton works as a cushion. Such structure also enables the concentrated treatment on the specific area on the skin very easily.

Claims 1, 3, 5-8 and 11 were rejected under 35 U.S.C. §103(a) as being obvious from newly cited U.S. Patent No. 4,372,098 to Mason in view of U.S. Patent No. 6,547,468 to Gruenbacher et al.

Mason discloses a method for manufacturing an applicator package including:

(a) two separable webs of material (cover sheets) made of plastic sheets, and

(b) an applicator pad impregnated with an antiseptic liquid, such as iodine, which is injected into recesses where the pad is disposed through the manufacturing process.

To keep it hermetically sealed, the surrounding part of the cover sheet is sealed by means of heating dies.

Mason ONLY discloses the simple structure of an applicator, but fails to disclose or even remotely suggest either a pouch or blister, as claimed herein.

In this regard, Mason is substantially the same as previously applied U.S. Patent No. 5,562,642 to Smith et al which was also combined with U.S. Patent No. 6,547,468 to Gruenbacher et al. See the Office Action of August 30, 2007.

The remarks made in the Amendment filed in response to the latter Office Action apply equally herein, and as a result of these remarks, Smith et al was removed as a reference. The same should apply here.

It should be further reminded that NOWHERE in Mason is there a statement of even a remote idea or implication regarding a pouch or blister by which a skilled person in the art would be motivated to provide the same.

In fact, Smith et al, which is virtually the same as Mason, states that a package equipped with a breakable reservoir therein having a weak point is improper to use due to unexpected rupture or leakage in transportation. Specifically, Smith et al states at column 3, lines 11-22: "... problems may occur because of

premature leakage or evaporation of the liquid contents from the inner chamber of the dispensing package into the external applicator due to a premature break in the fracture line. If the overwrap becomes torn or punctured, the applicator may become uncovered and contaminated, and the liquid substance prematurely dispensed."

Further, Smith et al states at column 3, lines 45-50: "A disadvantage of packaging devices that release their contents by rupturing a score line in the container wall is that flexing of the package prior to use may cause the fracture line to split apart prematurely, thus causing unwanted leakage or premature dispersal of the contents. Conversely, the score line may be constructed such that it is difficult to break."

Therefore, Smith et al designed the system thereof to avoid these problems in a system of the type disclosed by Gruenbacher et al. See column 3, lines 51-63 of Smith et al.

There is thus evidence in the prior art, namely, Smith et al against combining Mason with the rupturable blister of Gruenbacher et al. Thus, one skilled in the art, upon reading Smith et al and Mason, would seek to avoid the structure of Gruenbacher et al.

Upon this background, Smith et al adopted use of an immersed pad 20, 22, instead of such a reservoir, capsule, ampule or blister, in order to avoid this risk. The same was done in Mason.

Since Smith et al is virtually the same as Mason, there is a teaching away in the art from using a blister as in Gruenbacher et al in place of the single impregnated pad of Smith et al or Mason.

Further, although it is further stated in the Office Action that "Mason teaches closed outline junction line 24 surrounding the applicator in an area significantly greater than the applicator area 20", there is NO disclosure showing such an arrangement of "significantly greater than".

In this sense, Mason completely teaches away from the present invention as to this aspect as well.

In summary, as to Mason:

- a) Mason fails to disclose the claimed blister,
- b) Mason fails to disclose the claimed pouch, and
- c) there is a teaching in the art (Smith et al) away from using a blister in place of the impregnated pad of Mason.

Further, since the combination of Smith et al and Gruenbacher et al was previously removed as being overcome, the same should apply to the combination of Mason and Gruenbacher et al, for the same reasons.

Gruenbacher et al discloses a dosing reservoir with a liquid permeable sheet 15 and a breakable cell 12 therein. This dosing reservoir consists of two separated chambers 12, 18 before use.

These chambers are formed by a permanent seal in one part 13, 16 and a weak seal in another part 14. Furthermore, the

stress concentrator is formed on the weak seal line to control the liquid flow.

More specifically, these are sealed to form a permanent seal in sections 13, 16 to bind two flexible films and a permeable membrane (three layers), and to form a frangible or weak seal in the other section 14 to bind a flexible film and a permeable membrane (two layers). As a result, part of the cell of Gruenbacher et al is detachable.

The two chambers of inner cell 12 and outer cell 18 are formed on the common flexible film. With this arrangement, cell 12 is **NOT** completely surrounded, as with the present claimed invention. This is because, as shown in Figs. 2 and 2A, both upper sheets 15 and 25 are secured at the same location to lower sheet 25 at sections 13, 16, so that cell 12 formed by sheets 25 cannot be completely surrounded by the pouch, as recited in the claims herein.

As such, a much more complicated structure is required comprising permeable sheet 15 and two impermeable flexible films 25 to form both a permanent seal and a weak seal in a different manner.

Gruenbacher et al apparently intends to achieve controlled flow when the cell (blister) is broken under compression with the structure mentioned above.

With the structure suggested by Gruenbacher et al, it would be difficult to impregnate most of the surface area of permeable

membrane 15. The reason is that the substance contained in the cell 12 is controlled to flow towards the second cell 18 only horizontally through the stress concentrator 17 after the detachment of the cell, and thus it would impregnate the permeable membrane only within a limited area. Moreover, a substance other than a liquid CANNOT be applied with the complicated structure of Gruenbacher et al. Accordingly, Gruenbacher et al lacks versatility as an applicator.

The Combination Mason with Gruenbacher et al

It was stated that "one of ordinary skill in the art would have found it obvious to mount the impermeable first part 25 of Gruenbacher to the inside face of Mason."

However, it is first noted that Gruenbacher states in background of the invention that "These capsules do not allow for controlled, dosed release of the active composition" (column 1, lines 20-21). See also column 1, lines 39-40: "Rupturing of the packet results in the unregulated flow of the packet contents..."

In short, Gruenbacher et al states that an uncontrolled blister or capsule CANNOT be used for applicator use in view of the flow controllability.

On the other hand, in the present invention, the blister gives rise to uncontrolled flow under breakage, and as a result, the blister must be completely surrounded by the pouch on all sides to avoid any loss of substance.

Secondly, as previously mentioned, Gruenbacher et al has disclosed the very complicated structure of a dosing reservoir to achieve controlled flow after breakage of the cell.

To produce such a reservoir with this constitution, appropriate materials must be selected and processing conditions, such as temperature, time and pressure must be controlled very strictly.

Considering the above, much more complex processes will be required and the yield will be lower with Gruenbacher, and thus, will result inevitably in higher cost.

Moreover, from the user's point of view, even if Mason was combined with Gruenbacher et al, it would be very difficult to operate and it would not work well when in use as it lacks versatility.

Therefore, it is submitted that one skilled in the art of single-use packages would not be inspired or motivated to combine Mason with Gruenbacher et al. The combination of Mason with Gruenbacher et al will not make sense from a practical standpoint.

Accordingly, there is NO logical reason to combine Mason with Gruenbacher et al, considering all of the above points.

Thus, the present claimed invention provides clear distinctions over the cited references.

In addition to the clear distinctions of the combination provided above of:

a) the protective cover made of two separable parts of leakproof material,

b) the breakable leakproof blister,

c) the pouch, and

d) the blister housed in the pouch with said pouch completely surrounding the blister on all sides thereof,

e) the teaching away in the art (Smith et al) from using a blister arrangement (Gruenbacher et al) in place of an impregnated pad (Mason), and

f) the teaching away of using an uncontrolled blister by Gruenbacher et al in view of the flow controllability, the present invention provides additional distinctions over this combination as follows.

With the present invention, a first additional difference lies in the structure of the blister. The blister in the present invention is formed only by a permanent seal around it, whereas the blister in Gruenbacher et al is formed by a weak or frangible seal (14) and a permanent seal (13, 16) in view of the requirement in Gruenbacher et al of a controlled flow. Gruenbacher et al clearly denies the conventional uncontrolled capsules (including the blister of the present claimed invention) as stated therein: "These capsules do not allow for controlled, dosed release of the active composition" See column 1, lines 21-22 thereof.

As to the permanent seal of the blister of the present invention, support is found at page 4, lines 18-20 which states that the blister cannot be detached from the protective cover 12. Rather, the blister is described as breakable (page 4, line 25). This is different from Gruenbacher et al in which the upper sheet 25 which forms the cell 12 or blister is detached at the frangible seal 14 to provide a release of the substance.

The applicants herein do NOT intend the controlled flow from the blister after breakage, but instead, intend that the substance is trapped by the pouch comprising the porous material, whatever the breaking point may be. For this reason, the pouch completely surrounds the blister on all sides thereof. Preferably, the blister is located at the central position of pouch.

On the other hand, the blister in Gruenbacher et al has a much more complicated structure in order to achieve the controlled flow, and as such, producing such complicated blister will require too much cost. Moreover, as the flow of liquid therefrom is controlled towards a specific direction (i.e. the horizontal or lateral direction), the surface for application is only partly impregnated with liquid after breakage of the blister.

Therefore, the skilled person in this art would NEVER be inspired to combine Mason with Gruenbacher et al.

In this regard, a new independent claim 12 has been added which recites the limitations of claim 1, and further recites that limitation that "said blister is entirely non-detachably fixed to one of:

a) said pouch, and

b) said protective cover."

In other words, in the embodiment of Fig. 3, the blister is entirely non-detachably fixed to sheet 24 of the pouch. However, if the pouch is only formed with the top sheet 24 secured directly to sheet 13, then the blister would be entirely non-detachably fixed to sheet 13 of the protective cover.

Thus, the package according to the present claimed invention comprises a protective cover, pouch and blister (which can be a conventional blister), wherein the blister is entirely surrounded by the pouch on all sides and entirely permanently secured (non-detachable) therein, and the pouch is adhered to one of the inside faces of protective cover. There is also NO need to control flow from the blister based upon the simple but rational structure. Consequently, when in use, if the user compresses the blister without opening the protective cover, the blister will break (the breaking point is not controlled) and the substance will impregnate the applicator of the pouch entirely. After that, the user will peel off the protective cover, and hold the protective cover. Thus, the user can apply the substance onto the skin without touching the applicator or substance. No

complicated structure is required to achieve such usability according to the claimed construction of the present invention.

Moreover, the blister can contain ANY type of substance, such as a powder, paste, liquid, etc. With the structure of the package of the present claimed invention, ANY kind of substance is easily applied on the skin, whereas the applicator according to Gruenbacher et al cannot apply substances such as a powder on the skin, because the flow is controlled. In other words, the substance will not flow but will remain within the restricted region. Meanwhile, both Mason and Kerch teach the applicator impregnated ONLY with liquid.

A second additional difference is that the pouch according to the present invention contains the blister shown in Fig. 3. As a result, the shape of the applicator has a convex or round shape. In the preferred embodiment, the pouch further contains cotton wool. Because of this arrangement, a user can selectively apply any substance even onto a narrow region on the skin, with soft feeling due to the cushion effect of the cotton. Of course, the user can also apply any substance onto a wide area of the skin.

On the other hand, both applicators of Mason and Kerch are flat or planar, and it is impossible to apply a substance onto a narrow area. In this sense, the package of the present claimed invention clearly has versatility and thus, provides an important advantage.

New dependent claim 13 covers this arrangement.

It is evident that the present claimed invention has many more technological advantages than any of cited documents or combinations thereof. No cited documents disclose or even remotely suggest or motivate the skilled artisan to be induced to the structure of the package of the present claimed invention, as well as the advantages thereof.

Accordingly, it is respectfully submitted that the rejection of claims 1, 3, 5-8 and 11 under 35 U.S.C. §103(a) has been overcome.

Claim 4 was rejected under 35 U.S.C. §103(a) as being obvious from Mason and Gruenbacher et al as applied above and further in view of U.S. Patent No. 4,762,124 to Kerch et al.

The remarks previously made above in regard to Mason and Gruenbacher et al are incorporated herein, and are therefore not repeated.

Kerch et al only discloses a pouch in which the cotton pad impregnated with liquid is wrapped with two separable impermeable sheets. The permeable membrane is further disposed between one of the impermeable sheets and the pad. The shape of the pad is entirely flat or planar, as shown in Figs. 2-4 thereof.

In none of the figures or the specification of Kerch et al is there any disclosure or even a remote suggestion of a blister. As such, Kerch et al suffers from the same deficiencies as Mason.

Therefore, it is submitted that one skilled in this art would not be inspired to combine Kerch et al with Gruenbacher and/or Mason.

Comparing Kerch et al with the present invention, Kerch's pouch only enables a user to apply a liquid substance to a wide area on the skin, whereas the applicator of the present claimed invention enables a user to touch up even a narrow area or spot area on the skin, such as a wound, without pain.

Accordingly, it is respectfully submitted that the rejection of claim 4 under 35 U.S.C. §103(a) has been overcome.

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being obvious from Mason and Gruenbacher et al as applied above and further in view of U.S. Patent No. 6,695,515 to Fleury and U.S. Patent No. 5,511,689 to Frank.

The remarks previously made above in regard to Mason and Gruenbacher et al are incorporated herein, and are therefore not repeated.

Fleury fails to disclose or even remotely suggest the limitations of a pouch fixed to the inside face of one of two separable parts, with the pouch comprising an applicator, and the blister being housed in the pouch, such that the applicator is impregnated with the substance when the blister is broken. Rather, at most, Fleury discloses two separable parts with a

blister therein, without any further structure of the claimed pouch.

Frank was merely cited for teaching an adhesive dressing 1 and cover 4 applicable to the external surface of a film 6 with the outside surface of dressing 1 weakly secured to an inside face cover 4. However, Frank al fails to cure any of the aforementioned deficiencies of Mason and Gruenbacher et al.

Accordingly, it is respectfully submitted that the rejection of claims 9 and 10 under 35 U.S.C. §103(a) has been overcome.

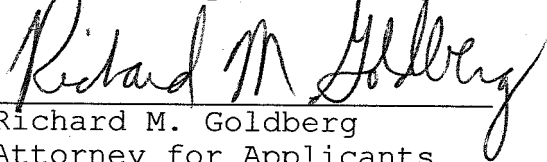
If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1 and 3-13 are allowable, and early and favorable consideration thereof is solicited.

Respectfully submitted,



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